Project Title: The TRIPS Agreement three-step test and the case of the R&D and diagnostic use exceptions.[1]

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Abstract: The project highlights that the interpretation of article 30 of the TRIPS Agreement, developed by a panel report of the World Trade Organization (WTO) in *Canada – Pharmaceutical Patents*, is legally unsustainable, and, therefore, should be ignored by the Member States of the WTO. The project posits a new interpretation to the terms of art. 30 of the TRIPS Agreement, which is solidly based on the case-law of the WTO Dispute Settlement Body (DSB). In order to prove that the TRIPS Agreement offers to its parties an ample policy room for the adoption of robust patent exceptions, the project proposes two exceptions –a so-called R&D exception and an exception for diagnostic tests. Both of them fully meet the requirements set by article 30 of TRIPS, when its terms are interpreted properly.

Keywords: Article 30 of the TRIPS Agreement, patent exceptions, access to patented knowledge, Vienna Convention on the Law of Treaties.

I. The Research Problem

Until not long ago, the patent system only extended legal protection to inventions that were characterized as end-consumers products, excluding natural phenomena and pre-existing natural resources from the list of materials eligible for protection. Therefore, only tangible products developed were eligible for protection; techniques of extraction of biochemical molecules in their natural environments were also eligible for protection, while the natural forces and resources as well as the technical information that permeates patented inventions were kept in the public domain. This was the means used by patent law to keep large spaces for the business sector to develop alternative products. This fact justified the adoption of research exceptions of limited scope, since the freedom to innovate was not restrained by patents.

From the 1980´s, the fast and amazing scientific development of biological sciences urged the judicial and administrative authorities of industrialized countries and developing countries to reinterpret and/or amend its patent laws with the purpose of enabling the protection of inventions that by then were not considered eligible for protection. As a result, at present, many States provide protection to, inter alia, microorganisms, recombinant proteins, transgenic plants and animals, and sequences and DNA fragments including those of human origin.

[1] The original title of the project was "The functionality of the 'three-step test' in widening the scope of research exemptions: Transposing the copyright experience into the patent field."

Many of the inventions developed by the emerging sectors of the economy, notably, by the pharmaceutical and biotechnology industry, have special features: they can serve both as final products consumable by the ordinary consumer; they can also serve as inputs to the scientific community. Thus, it has disappeared the boundary between the consumer-end products and foundational developments.

One of the main consequences of the granting of patents for foundational developments is the establishment of potential obstacles to the scientific and technological progress of society. This is because patents confer on their owners not just the prerogative to effectively control the products developed, but also the freedom of others to innovate through the use of patented inputs.

Recalling that the technical-scientific development is a cumulative process, dependent on continuous access to a wealth of knowledge, the expansion of the reach of the private domain over foundational inventions, in the absence of robust patent exceptions, endangers the well being of substantial portions of humanity, especially those with lower purchasing power.

The research exception is one of the tools most commonly adopted by the international community to harmonize the interests of patent holders with those of society. Even though its scope varies in each jurisdiction, generally, they allow third parties to carry out scientific experiments on the protected invention, without the prior authorization of the patentee. The massive presence of research exceptions in national legal systems reflects the understanding that the scientific and technological development should not be controlled by patent holders.

Regardless of the peculiarities of each national law, research exceptions are designed to make room for society to generate new knowledge about the patented technologies and to allow the continuous development of new products and technologies from the contributions introduced by the patented objects. Specifically, research exceptions can promote at least three separate, but interconnected interests: enabling the scrutiny of patented inventions, generate new knowledge on the protected inventions and facilitate the development of subsequent inventions.

The great difficulty now faced by scientists and industrialists worldwide is that the expansion of the list of patentable subject matter was accompanied by a substantial reduction of the scope of research exceptions or by the preservation of the old “research exceptions”, which were adopted in a different scientific scenario. Consequently, nowadays, patent rights resemble a system of absolute property that provides its holders the right to control *all* forms of use of their patented inventions. There is, therefore, a need to devise new patent exceptions, more adequate for the present, marked by massive expansion of the list of subject matters eligible for patent protection.

II. Objectives

Any of the 153 Member States of the World Trade Organization wishing to adopt patent exceptions is obliged to observe the conditions laid down by Art. 30 of the TRIPS Agreement which states: "Members May Provide limited exceptions to the exclusive rights conferred by the patent, Provided That such exceptions to not unreasonably conflict with normal exploitation of the patent and the not unreasonably prejudice the

legitimate Interests of the patent owner, taking account of the Interests of third parties legitimate." The terms of this provision are hard to determine: there are no tips on how to interpret what is a "limited exception", or what is an "unreasonable conflict" with the normal exploitation of patents. These ambiguities offer to WTO Member States some latitude to interpret them so as to enlarge the space available for the adoption of exceptions to patent rights, truly capable of overcoming the problems raised by the contemporary patent regimes. However, in the only opportunity the WTO had to interpret the terms of art. 30 (Canada - Pharmaceutical Patents), the Panel adopted an extremely conservative interpretation, directed at over-protecting the economic interests of patent holders. Other important interests have been neglected in the process of interpretation.

Given this reality, the project has pursued as its main objective to study neglected flexibilities offered by the TRIPS Agreement to its Contracting Parties, which authorize the adoption of robust research exceptions. More specifically, the project explored the terms of the so-called "three-step test" in Article 30 of the TRIPS Agreement, and construed its terms in a manner which fosters the realization of the balance of rights enshrined in article 7 of the same agreement.

But acknowledging that lately the large trade players – i.e. the U.S., Europe and Japan - have been negotiating free trade agreements with developing countries containing "TRIPS-plus" rules, which, as its name hints, go beyond the obligations required by the Agreement TRIPS, the project also aimed to investigate if these free trade agreements set new barriers for a more liberal interpretation of the terms of the article 30 of the TRIPS Agreement.

All objectives set were successfully achieved. Firstly, the study identified an important but neglected tool of the TRIPS agreement: the obligation to interpret the terms of the TRIPS Agreement in accordance with the rules of treaty interpretation as laid down in the Vienna Convention on Law of Treaties (Articles 31 and 32). These rules, in fact, are not mere flexibilities offered to Member States of the WTO, because their observance is mandatory. However, both the Member States of the WTO as the organs that comprise the Dispute Settlement Body of the WTO (panels and Appellate Body) often flout these rules. The effect of these attacks is to restrict the space available for the establishment of strong exceptions to patent rights, able to promote, for instance, access to medicines and to proprietary knowledge.

The second finding of this study was that the free trade agreements containing "TRIPS-plus" provisions must observe the few, but important, "ceilings" set by TRIPS. These "ceilings" prevent the States Parties to negotiate new intellectual property obligations that hurt the social and economic goals of the TRIPS Agreement and the WTO. This, in practice, means that WTO members may not negotiate TRIPS-plus agreements that breach the terms of art. 30 of TRIPS.

III. Methodology

To achieve the objectives outlined, the main research method used was to review the literature about the proper application of the rules of treaty interpretation, enshrined in Articles 31 and 32 of the Vienna Convention on the Law of Treaties, and to review the

case law of the system of disputes settlement of the WTO. These methods allowed for the reinterpretation of terms of art. 30 of TRIPS in an innovative manner. The new interpretation proposed departs from the one put forward in Canada – Pharmaceutical Patents, and indicates that many of the problems associated with the TRIPS Agreement are due to the lack of ability to interpret its terms in a correct and balanced way, and not to some intrinsic imbalance of the agreement. The research methods, though simple, were the most appropriate as they allowed the construction of a new interpretation of the terms of art. 30 based on the instruments that the WTO Members are obliged to use: the rules of interpretation of the Vienna Convention and the jurisprudence of the WTO.

In principle, it was proposed to carry out interviews with research institutions in Brazil, to investigate the difficulties faced by the Brazilian scientific community to conduct scientific research in the field of life sciences. However, we had insurmountable difficulties: most of the researchers and institutions approached refused to grant interviews, and the few people who agreed to be interviewed for the project, in practice, proved unavailable. Anyway, the international literature on the real obstacles raised by contemporary patent regimes for the advancement of science and technology is wealth. Thus, the change in methodology has not symbolized a loss of quality of the project.

IV. Project Activities

The funds transferred by the International Development Research Centre were mainly used to pay the costs of salaries of the principal investigator (Edson Beas Rodrigues Jr.) for a period of approximately 22 months (full time), and the scholarship granted to his research assistant. Another part of the funds transferred have been used by the partner institution (McGill University) to fund the preparation of a case study on research exceptions in Mexico.

V. Project Output

The main research result of the project concluded on 30 April 3010 is a book, which should be published in Portuguese and in English, about art. 30 of the TRIPS Agreement. This book, besides explaining, in detail, the correct method of interpretation of the provisions of the TRIPS Agreement, also built a new interpretation to the terms of art. 30, and proposed two exceptions to patent rights: a Research & Development exception and an exception for diagnostic testing. Both exceptions proposed successfully pass the test of art. 30 of the TRIPS Agreement. After completion of the project, the principal investigator decided to make new additions in order to make it the most comprehensive as possible.

The results of the project have not been disclosed so far, but there is an expectation that the work will influence the results of new litigations that may be brought before the WTO regarding the terms of art. 30 of the TRIPS Agreement. And most importantly, there is an expectation that the research output will affect developing countries and even industrialized countries, and persuade them to adopt exceptions to patent rights more appropriate to deal with the new problems raised by the contemporary patent regimes.

VI. Overall Assessment and Recommendations

Provisional results of the project were presented in October 2009, at IDRC headquarters in Ottawa for a select group, formed by IDRC staff and grantees who received funds under the auspices of the project "Accessing Patented Knowledge." The exchange of information and knowledge that took place at that time influenced the improvement of the project and its results. For this reason, I suggest IDRC keeps encouraging greater exchange of information and experience among its grantees that are carrying out projects on related issues.

The project consumed more time than expected (22 months, and initially was expected to consume 18 months). Anyway, I believe the project was a success, from the viewpoint of the interests of developing countries: the final results indicate that there is a fertile field available to policy-makers from developing countries and industrialized countries for the enactment of new statutory exceptions to patent rights, truly robust and able to create a balance between the economic interests of patent holders and the interests of the society to substantially broaden access to knowledge for scientific and productive goals. This conclusion is not trivial: in general, developing countries and NGOs consider that the TRIPS Agreement would need to undergo substantial reforms, so it can be used as a tool for promoting sustainable development. This observation, however, is not valid in regard to space for the adoption of exceptions to patent rights.